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France: A step towards more regulated drug prices

2022 was an expensive year for public spending in France, that led to a €18.9 billion debt for the social security system[1], of which almost 90% was driven by health-related spending[2]. The 2023 social security financing law, Loi de Financement de la Sécurité Sociale (LFSS), approved by Parliament on 23 December 2022, aims to reduce debt to €7.1 billion, with the 2023 budget set at €244 billion. While savings are not expected to affect hospital spending, the government hopes to reduce costs of pharmaceuticals, laboratory testing, imaging and complementary healthcare[1].

Among key reforms that are likely to affect pharmaceutical manufacturers is the initiative to increase prevention and, more specifically, the expansion of immunisation competencies for nurses, pharmacists and midwives for people aged over 16. This validates the recommendation made by the Haute Autorité de Santé (HAS) in June 2022[3] to improve immunisation coverage and the immunisation pathway[4].

Another key aim of the LFSS is to renew the regulation of innovative expenditure including gene therapies. Art. L. 162-16-6 explains that when the price charged by the manufacturer exceeds a threshold set by ministerial order, the treatment cost will be determined by agreement or, failing that, by decision of the Comité Economique des Produits de Santé (CEPS, pricing committee). Additionally, a cap will be fixed as the maximum treatment costs to be paid for each patient. If prices exceed the per-patient cap, performance-based payment models could now be applied to mitigate for the excess

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[1] Vie Publique (2022). Loi du 23 décembre 2022 de financement de la sécurité sociale pour 2023. Accessible from: https://www.vie-publique.fr/loi/286458-loi-23-decembre-2022-financement-securite-sociale-2023-budget-secu-plfss

[2] Projet de loi de financement de la sécurité sociale pour 2022 (n.d.). Accessible from: http://www.senat.fr/rap/a21-122/a21-1223.html

[3] Haute Autorité de Santé (HAS) (2022). Élargissement des compétences en matière de vaccination des infirmiers, des pharmaciens et des sages-femmes chez les adolescents de plus de 16 ans et les adultes. Accessible from: https://www.has-sante.fr/jcms/p_3312462/fr/elargissement-des-competences-en-matiere-de-vaccination-des-infirmiers-des-pharmaciens-et-des-sages-femmes-chez-les-adolescents-de-plus-de-16-ans-et-les-adultes.

[4] Légifrance (2022). LOI n° 2022-1616 du 23 décembre 2022 de financement de la sécurité sociale pour 2023 (1). Accessible from: https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000046791754

and reimbursement could be terminated if the product is not effective, if the patient dies or if another treatment with the same therapeutic aim is administered[4,5,6].

The LFSS also introduces a new regulation around the price negotiation of pharmaceuticals. In the scenario where the manufacturer requests reimbursement of its product for only part of the labelled indications, with the drug receiving a sufficient medical benefit rating (Service Médical Rendu, SMR) for the remainder of the labelled indication(s),
Art. L. 162-18-2 requires rebates on the price for the indication(s) which were not requested by the manufacturer, until they are submitted for reimbursement. The level of rebates will be determined by "applying to the revenues a rate defined by the size of each of the target populations of the indications that were not requested, or, failing that, according to a progressive scale, by revenue threshold, defined by this same decree". The revenues should be communicated by the company to CEPS annually[4].

Healthcare spending soared in 2021 following the COVID-19 pandemic and the rising costs of orphan drugs and cancer medicines, while new regulations (i.e., Accord Cadre) now guarantee stability of prices and benchmark prices to other European countries[7]. In this context, the French Government, via the LFSS, aims to keep budget spending and drug prices under control, without compromising patient access to innovative treatments.

The LFSS was approved in a context of similar reforms in neighbouring countries. For example, in Germany, the GKV Financial Stabilization Act (GKV-FinStG) introduced new restrictive pricing specifications for reimbursement negotiations[8]. Similarly, in Spain a Royal Decree Regulating the Funding and Pricing of Medicines and Health Products is expected to be published later this year to introduce new reserves and conditions for funding medicines[9].

While these reforms differ in their approach across countries, they all have a specific aim, namely, to reduce healthcare budget spending. Whilst this is not surprising after the much-needed pandemic splurges in spending of the past couple of years, it highlights a European trend towards a more regulated pricing process. In France, this heralds an era of growing price opacity, with rebates on non-reimbursed indications and confidential performance agreements adding to the lack of transparency of the system.

Authors

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[5] GD Avocats (2022). PLFSS: CRÉATION D'UN MODE DE FINANCEMENT SPÉCIFIQUE POUR LES MÉDICAMENTS DE THÉRAPIE INNOVANTE. Accessible from: https://www.gd-associes.com/actualites/plfss-creation-dun-mode-de-financement-specifique-pour-les-medicaments-de-therapie-innovante-mti/

[6] GD Avocats (2023). LFSS 2023: QUAND LES NOUVELLES MESURES SERONT-ELLES APPLICABLES? Accessible from: https://www.gd-associes.com/actualites/lfss-2023-quand-les-nouvelles-mesures-seront-elles-applicables/

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[8] VFA (2022). Medizinische Versorgung als erstes Opfer des GKV-Finanzgesetzes? Accessible from: https://www.vfa.de/de/wirtschaft-politik/amnog/medizinische-versorgung-als-erstes-opfer-des-gkv-finanzgesetzes

[9] Administracion General del Estado (2023). Accessible from: https://www.lamoncloa.gob.es/consejodeministros/resumenes/Documents/2023/310123-PAN2023.pdf

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